Atty. Docket No. Case 25/NP PREC

DRIVE SHAFT COUPLING

RELATED APPLICATIONS

This application is a continuation-in-part of Ser. No. 09/860,916, filed May 18, 2001 and entitled, "Stress-Induced Connecting Assembly", which is a continuation-in-part of Ser. No. 09/523,719, filed March 11, 2000 and entitled, "Stress-Induced Interposed Connector" (U.S. Patent No. 6,257,953), which is a continuation-in-part of Ser. No. 09/311,938, filed May 14, 1999 and entitled "Stress-Induced Seal", now abandoned. This application is further based on prior Provisional Application Ser. No. 60/262,362, filed January 19, 2001 and entitled Drive Shaft Coupling. The entire disclosures of these afore-mentioned applications are expressly incorporated by reference herein and relied-upon.

TECHNICAL FIELD

This invention relates generally to torque-transmitting assemblies that have fittings coupled to a flexible drive shaft made of a super-elastic alloy, useful in devices for medical and industrial applications where a flexible shaft is necessary; and in particular to powered surgical instruments for transmitting torque to "flexible reamers" or "flexible drills" to remove material from the center of curved bones during orthopedic surgery.

BACKGROUND OF THE INVENTION

It is commonly known that nitinol (nickel-titanium) tubing, wire or rod can be used as a mechanical drive shaft. Nitinol is especially useful for transmitting torque while in a bowed or bent shape. These types of drive shafts have proven useful in orthopedic surgical applications where drilling or reaming of curved bones is necessary. One application is to use a drill or reamer with a nitinol drive shaft to clean out the center

of a femoral bone before implanting a prosthesis or femoral nail. These bones typically have a bow with a 90-inch radius and require a flexible reamer for the procedure. Nitinol tubing can be used for this application since it is cannulated and can be passed over a guide wire that is placed down the femur before the reaming process begins. Since the tubing is solid it is very easy to clean after the surgical operation since there are no crevices for blood to get trapped in. Earlier designs utilized spring drive shafts and cleaning was extremely difficult since blood could get trapped between the windings of the spring. The earlier spring designs also had difficulties when run in the reverse direction since springs tend to be strong while being used in one direction, however when run in the opposite direction they tend to unwind. To prevent this unwinding problem several manufacturers have added an additional spring inside of the primary spring, which is wound in the opposite direction. Since one spring is inside of the other this contributes to the difficulties with cleaning and further obviates the need for an alternative shaft design.

With the market demand increasing for these novel nitinol drive shafts there have been many attempts to develop safe coupling methods for attachment to the shaft. One difficulty that engineers have been faced with is presented when nitinol tubing exceeds its torsional or fatigue stress limits; it has been known to fail catastrophically and fragment into several sharp pieces. This is dangerous when inside of a patient and poses severe concerns if these types of products are to be used reliably. Historically there have been no solutions offered to limit the stress in the drive shaft, which would eliminate the presently lingering concerns over breakage during use.

Another difficulty is presented with the attachment of the fittings to the nitinol drive shaft. The connection must be reliable and not create any unnecessary stress on the tubing. This will lead to early failure of the shaft. Typically in the orthopedic reamer example mentioned above one end of the nitinol tube has a stainless steel fitting which attaches to a power instrument and on the opposite end either a stainless steel reamer head or an intermediate modular fitting that connects to a reamer head. Several attempts to create reliable attachments have been made.

One approach to the above-mentioned attachment problem has been to use an epoxy to “glue” the fittings onto the nitinol shaft. However, temperatures in the

sterilization process and the criticality of surface preparation have rendered this approach unreliable.

Another approach has been to attach the fitting to the shaft with a laser weld; however, the welding process embrittled the tubing and it was known to fail torsional demands in testing. A cross hole and pin were placed through the fittings, however this added approach further proved useless since the matching hole in the tubing created a tremendous stress riser in the tubing causing failure at very low torsional values. In the example mentioned it was known to fail anywhere between 2 to 4 N-M.

Yet another approach has been to press fit the nitinol shaft into a fitting with approximately .002-inch interference. Initial trials worked, however when put through rigorous fatigue tests the tubing placed too much hoop stress on the fittings causing them to fail rather than the shaft. The solution proposed to fix that problem was to add a long section on the fitting that was loosely fit around the tube. This would allow the stress to transition slowly into the area where the press fit was done. This worked successfully, however the solution created a need for the fitting to be extremely long in comparison to the reamer heads being used. This is undesirable since the reamer must follow the curvature of the bone and it did not solve the issue of limiting the torque in the shaft to ensure the safety of the drive shaft during use.

Thus, there remains a primary need to provide a coupling system that is safe and effective for use in surgical and industrial applications where flexible drive shafts are necessary.

There is another need to use a nitinol drive shaft to replace the spring drive shafts in orthopedic instruments and many industrial tools to simplify the cleaning process and ensure consistent torque resistance in the forward and reverse directions.

There is a further need to provide a coupling system which will limit the torque in the nitinol drive shaft fitting to ensure that the coupling limits the torque before the tubing breaks.

There is yet a need for a coupling that will not place any unnecessary stress on the nitinol tubing causing it to prematurely break.

There is also a need to shorten the length of the fitting so that the reamer can follow the natural contour of the inside of the bone while transferring the stress smoothly so as to ensure the strength of the fitting.

SUMMARY OF THE INVENTION

According to the invention, a torque-transmitting assembly is described, as well as a method of forming the assembly and a surgical reamer that includes the assembly. The assembly has a female coupling member with a bore. The female coupling member may be a fitting that connects to a power instrument or it may present a cutting head, or both. A radially flexible member is received within the bore, defining a hollow shape with an opening. The assembly also has an elongated shaft member made of a super-elastic alloy, received within the opening. Relative motion among the members causes the radially flexible member to contact the shaft, inducing a super-elastic activation in the shaft that urges the shaft and radially flexible member into surface-to-surface contact, securing the members together in a fixed relative position. In a preferred embodiment, the radially flexible member has an external surface that frictionally engages the bore upon relative motion. The contact still preferably occurs along one or more areas that frictionally carry the applied torque, which contact area may be calibrated so that the contact slips at a preset torque before the failure strength of the shaft is reached. In another preferred embodiment, the shaft is tubular with a cannulation, which may further be aligned with another cannulation in the female coupling member for common passage of a guide wire. In yet another preferred embodiment, an inter-positional polymer sleeve is provided in the assembly for transmitting bending stress. In a still another preferred embodiment, the female coupling member has a counter-bore, while the radially flexible member has an exterior surface adapted for engagement within the counter-bore and may be compressed within the counter-bore or be in a pre-assembled state therein. In one alternative, preferred embodiment, the radially flexible member has a split collet, whereupon relative motion among at least two of the members causes the opening to contact the shaft, inducing a super-elastic activation in the shaft that urges the shaft and the collet into surface-to-surface contact, securing the members together in a fixed

relative position. In another alternative, preferred embodiment, the radially flexible member is a collar and made of super-elastic alloy, whereupon relative motion between the fitting and the collar causes the collar to contact the shaft, inducing a super-elastic activation in the shaft that engages the shaft and collar into surface-to-surface contact, securing the members together in a fixed relative position. The collar may further be a washer or a series of washers.

A method of forming a torque-transmitting assembly is also disclosed, having the following steps. A female coupling member is provided, with a bore, as is a radially flexible member with an external surface and an opening, the radially flexible member being situated within the bore. An elongated shaft member is provided, made of a super-elastic alloy, and is received within the opening. Relatively moving at least two of the members, causes the radially flexible member to contact the shaft, inducing a super-elastic activation in the shaft that urges the shaft and radially flexible member into surface-to-surface contact, securing the members together in a fixed relative position. The radially flexible member may alternatively consist of either a split collet operable with an outer compression sleeve, or a super-elastic collar operable within a counter-bore of the female coupling.

A flexible surgical reamer having a torque-transmitting assembly is also disclosed. The assembly includes a female coupling member, which may be a fitting with a counter-bore that is further provided with a head presenting a cutting tool-bit, or may be an outer compression sleeve. A radially flexible member is provided, which may be a collar member made of super-elastic alloy with an opening, preferably a washer or series of washers, located in the counter-bore. Relative motion among the members causes the opening to contact the shaft, inducing a super-elastic activation in the shaft that urges the shaft and the collar into surface-to-surface contact, securing the members together in a fixed relative position. Alternatively, the radially flexible member may have a split collet with an exterior surface received in the sleeve, and an opening. The assembly has an elongated shaft member made of a super-elastic alloy, received within the opening. Relative motion among the members causes the opening to contact the shaft, inducing a super-elastic activation in the shaft that urges the shaft and the collet into surface-to-surface contact, securing the members together in a fixed relative position.

It is desirable that the contact occurs along an area that frictionally carries the applied torque and is calibrated to slip at a preset torque before the failure strength of the shaft is reached. An inter-positional polymer sleeve may be additionally provided for transmitting bending stress in the assembly. The shaft may be tubular, with a cannulation, likewise the female coupling member may have a cannulation that aligns with the shaft cannulation for passage of a guide wire through the reamer.

An advantage of the present invention is a torque-transmitting coupling assembly that is also torque-limiting, relying upon a surface-to-surface frictional contact, thus slippage of the coupling occurs at torque less than the maximum failure strength of the shaft.

Another advantage of the present invention is that the torque can be adjusted, by increasing or decreasing the area of contact in interference and adjusting the surface finishes on the assembly components.

A further advantage is the amelioration of fatigue due to hoop stress by use of a preferred softer material, such a polymer sleeve interposed between the coupling member and the shaft-- this acts as a dampener to spread out the forces smoothly ensuring the proper stress transfer.

Other objects and advantages of the invention will become apparent upon reading the following Detailed Description and upon reference to the appended Drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded view of a torque-transmitting assembly of the present invention, showing a preferred fitting formed with a split collet, a compression sleeve and an optional polymer sleeve interposed therebetween;

FIG. 2 is an elevational view of **FIG. 1**, showing the collet compressed by the sleeve to couple the assembly;

FIG. 3 is a sectional view taken substantially along the Lines **3-3** of **FIG. 2**;

FIG. 4 is an exploded view of another embodiment of a torque-transmitting assembly of the present invention, showing a fitting with a collar preferably having a

series of washers each made of super-elastic alloy, a compression sleeve and an optional polymer sleeve;

FIG. 5 is an elevational view of **FIG. 4**, showing the collar compressed by the sleeve to couple the assembly; and

FIG. 6 is sectional view taken substantially along the Lines **6-6** of **FIG. 5**.

DETAILED DESCRIPTION

Referring to **FIGS. 1-3** and particularly **FIG. 1**, the present invention includes a drive shaft **5** made of a super-elastic alloy, preferably a nickel-titanium commonly known as nitinol. Shafts made from this type of alloy can be formed with a cannulation **7** as shown in **FIG. 3** and exhibit the distinctive characteristic of transferring torque while subjected to high bending forces during use. The exemplary use of the present invention is in orthopedic drilling and reaming devices; however, the usage of super-elastic alloys according to the invention has much broader applications encompassing both medical as well as other industrial applications. A device of the present invention is generally shown at **13** in **FIGS. 2-3**. Tool fitting **20** preferably has a cannulation **22** that is aligned with another cannulation **7** formed in shaft **5** when device **13** is assembled according to the present method. The aligned cannulations **7, 20** allow device **13** to be placed over the top of a guide wire (not shown). Tool fitting **20** also has a radially moveable, i.e., flexible collet portion **25**, which is preferably an integral structure although the fitting may be separate from the radially flexible portion as discussed below in conjunction with another embodiment (**FIGS. 4-6**). According to the present method, shaft **5** is slid into collet **25**. Preferably there is an interference fit between the outer diameter **D1** of shaft **5** and the inner diameter **D2** of collet **25**. This interference causes collet **25** to bend out in a flower configuration as shaft **5** and fitting **20**, are slid together.

Once shaft **5** has been slid into collet **25**, a compression sleeve **10** (**FIGS. 1-3**) is slid over the flower shaped collet **25** and welded at junction **12**. As these components **5, 10, 25** are assembled, the collet **25** is forced radially onto the shaft causing a super-elastic activation of the alloy forming the shaft to thereby effect a secure coupling. This super-elastic reaction allows the fingers of collet **25** to contact the tube along the length **L1** as

shown in **FIG. 3**. This surface-to-surface contact (shown at **30** in **FIG. 3**) allows the device **13** to transmit torque. In essence the components are transmitting torque via friction. Thus, whenever the frictional forces are overcome by application of too much torque to the tool fitting **20**, the fitting and shaft **5** break free of one another to slip rotationally. This slippage limits the amount of torque that can be applied to the shaft. The contact surface **30** can be adjusted by design to change the length **L1**, in turn, adjusting the maximum applicable torque limit to ensure that the slippage occurs before the maximum yield strength is reached in shaft **5**.

Compression sleeve **10** may have an optional polymer sleeve **15** pre-assembled inside. The purpose of polymer sleeve **15** is to transfer stress through tool fitting **20** in a uniform manner to shaft **5** during its use in a bent configuration. This smoother transition ensures premature failure of fitting **20**. Use of polymer sleeve **15** may be found necessary when the design of the wall thickness of tool fitting **20** becomes thin, e.g., between about .25 mm to 1.00 mm. Otherwise, tool fitting **20** will be able to handle the stress eliminating the necessity for polymer sleeve **15**.

Another preferred embodiment of the present invention is depicted in **FIGS. 4-6**, particularly **FIG. 4**, which shows a shaft **105** made of super-elastic alloy such as nitinol. As discussed relative to **FIGS. 1-3**, shaft **105** is similar, preferably having a cannulation **107** as shown in **FIG. 6**. Shaft **105** thus can exhibit the distinctive characteristic of transferring torque while exposed to high bending forces during use. Although the exemplary uses of super-elastic alloy herein are orthopedic drilling and reaming devices, use of this alloy in the present invention has much broader applications encompassing both medical as well as other industrial applications. The assembled device is generally shown at **113** in **FIGS. 5-6** and utilizes a tool fitting **120** that is modular rather than a unitary component (see collet **25** in **FIGS. 1-3**). Tool fitting **120** may have a cannulation **122**, which is useful while aligned with the shaft cannulation **107** to allow it to be placed over the top of a guide wire (not shown). Tool fitting **120** is sized with inner diameter **D104** and has a modular radially flexible portion comprising a series of nitinol washers **125** that together are collar-shaped. Washers **125** each have an outer diameter **D103** and an inner diameter **D102**. During assembly according to another, preferred method of the present invention, shaft **105** having diameter **D101** is slid into the tool fitting **120**.

Preferably upon assembly there is an interference fit between the outer diameter **D101** and the inner diameter **D102** and an interference fit between the outer diameter **D103** and **D104**. This interference causes a radial compression in the flexible washers **125** causing surface-to-surface contact as shown at **130** along length **L101**. The radially flexible washers **125** end up interposed between the shaft **105** and the tool fitting **120**. This can be accomplished through various assembly methods. In one instance the flexible washers **125** can be pre-assembled with the tool fitting **120** and then the shaft **105** can subsequently be introduced to the assembly. Preferably though, the shaft **105** can be loosely placed in the tool fitting **120** and then the washers can be advanced into the tool fitting **120**. As they are slid into place they compress via interference between the outer dimension **D103** of the washers **125** and the inner dimension **D104** of the tool fitting. This interference causes a super-elastic reaction in the washers **125** causing their inner dimension **D102** to compress against the shaft's **105** outer dimension **D101** causing the surface-to-surface contact as shown at **130** along length **L101**. It is this surface to surface contact shown at **130** in **FIG. 6** that allows the assembly to transmit torque. In essence the components are transmitting torque-using friction. If the frictional forces are overcome by applying too much torque to the tool fitting **120** the components **120,105** break free and slip rotationally. This rotational slip limits the amount of torque that can be applied to the shaft. If the contact surface **130** is adjusted during design by changing the length **L101** the maximum applicable torque limit can be adjusted to ensure that the slippage occurs before the maximum yield strength is reached in the shaft **105**.

An additional sleeve **110** can be added and welded at junction **112** with an optional polymer sleeve **115** pre-assembled inside. The purpose of the polymer sleeve is to transfer stress through the tool fitting **120** in a uniform manner to the shaft **105** during use in a bent configuration. This smoother transition ensures premature failure of the fitting. The use of this polymer sleeve **115** may only be necessary when the design of the wall thickness of the tool fitting **120** becomes thin, somewhere on the order of .25 mm to 1mm. Other wise the tool fitting **120** will be able to handle the stress eliminating the necessity for the additional polymer sleeve **115** and sleeve **110**.

Although the invention has been described with reference to preferred embodiments thereof, it is evident to those of skill in the art that various modifications

and improvements may be made without departing from the spirit and scope of the invention as defined by the appended claims.